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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/993,371 | 11/13/2001 | Steinunn Backkeskov | 2307AA-043030US | 1403 |

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EXAMINER

MCGAW, MICHAEL M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1648

DATE MAILED: 06/16/2004

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/993,371

Applicant(s)

BAEKESKOV ET AL.

Examiner

Michael M. McGaw

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2003 and 03 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>06-12 and 08-03-03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment to the specification providing a specific reference, along with the relationship, to prior nonprovisional applications obviates the previous objection to that reference as originally found on page one of the specification. Furthermore, the amendment to the disclosure correcting the omission to parts of the reference citations obviates the associated rejection.

The amendment to claim 15 adding the word "purified" obviates the rejection under 35 U.S.C. 101 and the rejection under 35 USC 102(b) as previously anticipated by the human islet cells of Pak et al.

The rejection of claim 15 under 35 U.S.C. 112, 2nd paragraph is withdrawn in view of applicant's arguments, provided on page 4 of the reply filed October 3, 2003, regarding the meaning of the term "natural state" as used in the claim.

The rejection of claim 15 as anticipated by, or in the alternative, obvious over a 38 kD protein identified by Roep et al under 35 U.S.C. 102(b)/103(a) is withdrawn. Applicant has demonstrated that the reference protein, now known as Imogen 38, has been shown by Arden et al (J. Clin. Invest. 1996, 97(2):551;559) to have an estimated pI different from that of the product claimed by applicant.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1648

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 15 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ko et al or Pak et al for reason of record.

The declaration of Dr. Baekkeskov has been considered and is found to be not commensurate in scope with the claim. In applicant's response, and in the declaration of Dr. Baekkeskov, filed October 3, 2003, applicant points to characteristics that distinguish "Glima-38" from the reference proteins. However, the claim is not specifically directed to "Glima-38", but to any purified protein found in islet cell membranes with a MW of 38 kD, amphiphilic charge, pI of 5.4-6.1, and binds to autoantibodies. The October 3 response does not address the characteristics recited in the claim. In particular, the response fails to distinguish that which is claimed by applicant from the reference antigens.

Ko et al discloses a purified protein characterized in its natural state by a membrane-bound islet cell location and a molecular weight of 38 kD that specifically binds to autoantibodies. Ko is silent on the pI and the amphiphilic nature of the

Art Unit: 1648

reference protein. As for Ko et al, applicant responds that the reference antigen runs as a sharp band while Glima-38 runs as a diffuse band. Applicant's claim is silent as to Glima-38, but merely claims a purified protein found in islet cell membranes with a MW of 38 kD. Any limitation directed to the identity of the protein as Glima-38 or to the diffuse nature of the band does not appear in the claim. Applicant has also indicated that serum samples that recognize the reference protein were demonstrated to fail to recognize Glima-38. Again, no corresponding limitation is evident in a reading of claim 15. Therefore the argument fails to overcome the issue of the reference protein reading on claim 15.

Pak et al discloses a purified protein characterized in its natural state by a membrane-bound islet cell location and a molecular weight of 38 kD that specifically binds to autoantibodies. Pak is silent on the pI and the amphiphilic nature of the reference protein. Applicant asserts that the reference antigen and Glima 38 are different proteins because they exhibit different tissue expression patterns. In particular, while both are islet-cell associated, only Glima 38 is found in most brain tissue-derived neuronal and neuroblastoma lines. Additionally, applicant repeats that Glima 38 is found to run as a diffuse band whereas the reference antigen ran as a sharp band on SDS page. Again, claim 15 is not directed to Glima 38 to any purified protein found in islet cell membranes with a MW of 38 kD, amphiphilic charge, pI of 5.4-6.1, and binds to autoantibodies. The properties which distinguish Glima 38 from the reference protein are not evident as limitations in claim 15. Therefore applicant's argument fails to overcome the issue of the reference protein reading on claim 15.

On reconsideration, claim 15 is also rejected under 35 U.S.C. 102(b) as anticipated by DeAizpurua, et al. DeAizpurua et al discloses a purified protein characterized in its natural state by a membrane-bound islet cell location and a molecular weight of 38 kD that specifically binds to autoantibodies. DeAizpurua is silent on the pI and the amphiphilic nature of the reference protein. Even if the DeAizpurua protein runs as a sharp band on SDS page whereas applicant's 38kDa protein runs as a diffuse band, these are not distinguishing features for a purified protein found in islet cell membranes with a MW of 38 kD, amphiphilic charge, pI of 5.4-6.1, and binds to autoantibodies.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael M. McGaw whose telephone number is (571) 272-2902. The examiner can normally be reached on Monday through Friday from 8 A.M. to 5 P.M..

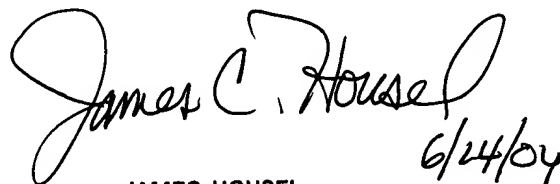
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1648

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Wednesday, May 19, 2004



6/24/04

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600